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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/649,134

08/27/2003

M. Ishaq Haider

P-5369A

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05/08/2006

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EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/649,134

Applicant(s)

HAIDER ET AL.

Examiner

Theodore J. Stigell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 7, 12-22 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-11, 23 and 25-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/9/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Oath/Declaration

The objection to the Oath has been withdrawn.

Specification

The objections to the Abstract and Specification have been withdrawn in light of the amendments.

Claim Objections

The objections to the Claims have been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Min (5,618,295). See Figures 2-6 and the respective portions of the specification. Min discloses a method for delivering insulin into the skin via an abrader device comprising the steps of positioning the abrader device with protrusions (48) at a delivery site, providing a housing (10) that holds the skin of a patient in place, and mechanically rotating microprotrusions (48) to disrupt and penetrate the stratum corneum to increase the permeability of the skin to insulin wherein the rotation is about an axis that is substantially perpendicular to the skin. The rotation of the microprotrusions creates

circular furrows, which can intersect each other to increase the surface area. See column 4, lines 32-60.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4, 6, 9, 10, 23, and 25-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Pistor (3,918,449) in view of Sage et al. (EP 1,086,719). Pistor discloses most of the limitations of independent claims 1 and 23. See previous rejection. However, Pistor does not teach to make the microprotrusions in a frustoconical shape. Sage et al. disclose a microabrader device that includes frustoconical microprotrusions. Sage et al. teach to use the frustoconical configuration to make burrows in the skin that are more absorbent to the applied medicament. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device and therefore the method of Pistor with the limitations as disclosed by Sage et al. to make a more effective method of delivering substances into the skin.

Claims 1-6, 11, 23, 25-26, and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Min (5,618,295) in view of Sage et al. (EP 1,086,719). Min discloses most of the limitations of independent claims 1 and 23. See previous rejection. However, Min does not teach to make the microprotrusions in a frustoconical shape. Sage et al. disclose a microabrader device that includes frustoconical microprotrusions. Sage et al. teach to use the frustoconical configuration to make burrows in the skin that are more absorbent to the applied medicament. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device and therefore the method of Min with the limitations as disclosed by Sage et al. to make a more effective method of delivering substances into the skin.

Claims 1-2,4,6,8,23, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garstein et al. (2004/0087992) in view of Sage et al. (EP 1,086,719). Garstein et al. disclose most of the limitations of independent claims 1 and 23. See previous rejection. However, Garstein et al. do not teach to make the microprotrusions in a frustoconical shape. Sage et al. disclose a microabrader device that includes frustoconical microprotrusions. Sage et al. teach to use the frustoconical configuration to make burrows in the skin that are more absorbent to the applied medicament. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device and therefore the method of Garstein et al. with the limitations as disclosed by Sage et al. to make a more effective method of delivering substances into the skin.

Response to Arguments

Applicant's arguments with respect to claims 1-11, 23-26, and 37-39 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to claims 27-36, filed 2/9/2006, have been fully considered but they are not persuasive. The Applicant seems to argue that none of the references cited meet the limitations of the perpendicular axis of rotation and the scraping edge but fails to provide specific arguments for each reference. The Examiner agrees that the Pistor and Garstein fail to meet the limitation of perpendicular axis of rotation, but the Examiner also contends that the Min reference meets both limitations. Evidence for this position can be found in the drawings and column 4, lines 53-67.


Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


NICHOLAS D. LUCCHESI
SUPERVISOR OF EXAMINER
TECHNICAL CENTER 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Theodore J. Stigell